The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

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Paper No. 46

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MANFRED BOHN,
KARL THEODOR KRAEMER, and
ASTRID MARKUS

Appeal No. 2004-0309
Application No. 09/077,194

HEARD: June 22, 2004

Before WINTERS, MILLS, and GREEN, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the examiner's final rejection of Claims 38-42, 48, and 53 -66, which are all the claims pending in U.S. Application No. 09/077,194.

Introduction

Claims 38, 39, 41, 42, 48, 53, 54, and 56-66 stand rejected under 35 U.S.C. § 103(a) as unpatentable in view of the combined teachings of Durrant et al. (Durrant),

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U.S. Patent No. 4,699,924, issued on October 13, 1987; and Lange, U.S. Patent No. 5,132,107, issued on July 21, 1992. Claims 40 and 55 stand rejected under 35 U.S.C. § 103(a) as unpatentable in view of the combined teachings of Durrant; Lange; and Saint-Leger, U.S. Patent No. 5,650,145, issued July 22, 1997, based on Application No. 08/435,806, filed May 5, 1995.

We have considered applicants' specification and claims, the applied prior art, and the positions of the examiner and applicants on appeal. On consideration of the record as a whole, we find that neither Durrant nor Lange constitutes the closest prior art. Saint-Leger, which was only applied against two dependent claims by the examiner, is the closest prior art. Accordingly, we vacate the examiner's rejections under 35 U.S.C. § 103(a).[1] We also enter the evidence submitted with applicants' Reply Brief received June 9, 2003, including the Declaration of Mitchell S. Wortzman, Ph.D, and exhibits A, B, and C attached thereto: A) Gerd Plewig & Thomas Jansen, Dermatology in General Medicine, 5th ed., CD-ROM (1999); B) Kenneth A. Arndt, Manual of Dematologic Therapeutics, 5th ed. (1995); and C) Handbook of Nonprescription Drugs (American Pharmaceutical Association, Washington DC 1996).[2]

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[1] As stated in Ex parte Zambrano, 58 USPQ2d 1312, 1313 (Bd. Pat. App. & Interf. 2001), "[t]he term 'vacate,' as applied to an action taken by an appellate tribunal, means to set aside or to void. When the Board vacates an examiner's rejection, the rejection is set aside and no longer exists" (footnote omitted).

[2] The exhibits attached to the Declaration of Mitchell S. Wortzman, Ph.D, will be cited herein as Exhibits A, B, or C. All references to page numbers of those exhibits are taken literally from the pagination provided by applicants.

We note applicants' commentary respecting commercial success during the hearing on June 22, 2004, but find no objective evidence of record in support thereof. As discussed more fully infra, we enter new grounds of rejection under the provisions of 37 CFR § 41.50(b).

The Claims

A correct copy of pending claims 38-42, 48, and 53-66 is found in Appendix B attached to applicants' Appeal Brief received December 16, 2002 (Paper No. 33).

Claim 39, the broadest claim on appeal, is directed to a method for treating a human or animal patient in need of treatment for seborrheic dermatitis by administering an effective amount of a composition comprising (1) at least one 1-hydroxy-2-pyridone having formula (I) and (2) at least one surfactant selected from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants.

Claim 38 differs from claim 39 by adding a limitation that the composition has a pH ranging from about 4.5 to about 6.5.

Claim 40 depends from claim 38 and adds the limitation "in which the at least one 1-hydroxy-2-pyridone of formula (I) comprises a cyclohexyl radical in the R^4 position."

Claim 48 depends from claim 38 and adds the limitation "in which the pharmaceutical composition further comprises at least one additional surfactant chosen from anionic, cationic, nonionic, and amphoteric surfactants."

Claim 59 is directed to a method for treating a human or animal patient in need of treatment for seborrheic dermatitis by administering an effective amount of a composition comprising (1) at least one 1-hydroxy-2-pyridone having formula (I), (2) at least one surfactant selected from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants, and (3) at least one keratolytic agent.

Claim 61 depends from claim 59 and adds the limitation "in which the at least one 1-hydroxy-2-pyridone of formula (I) comprises a cyclohexyl radical in the R^4 position."

Claim 53 is identical to Claim 59 except for an additional requirement limiting the composition to a pH ranging from about 4.5 to about 6.5.

Claim 55 depends from claim 53 and adds the limitation "in which the at least one 1-hydroxy-2-pyridone of formula I comprises a cyclohexyl radical in the R^4 position."

Claim 66 is directed to a method for treating a human or animal patient in need of treatment for seborrheic dermatitis by administering an effective amount of a composition comprising (1) at least one 1-hydroxy-2-pyridone having formula (I), (2) at least one surfactant selected from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants, and (3) lactic acid.

Claim 65 is essentially identical to Claim 66 except for an additional requirement limiting the composition to a pH ranging from about 4.5 to about 6.5,

Claim Interpretation

The claimed inventions are directed to methods for treating a patient in need of treatment for seborrheic dermatitis. We interpret the phrase "treating a human or animal patient in need of treatment for seborrheic dermatitis" as treating a patient afflicted with any form of seborrheic dermatitis for any one or more of the symptoms associated with that disorder.

We are mindful that applicants' specification defines seborrheic dermatitis as follows (Specification, p. 1, l. 3-7):

> Seborrheic dermatitis is understood as meaning a disorder of the scalp which differs from simple dandruff by the presence of erythema as a sign of inflammation, by the greater degree of scaling with occasional itching and burning, and by the occurrence of eczematous changes to other body sites.

Although seborrheic dermatitis may differ from simple dandruff in symptomatic degree or kind, nonetheless, applicants' claims are directed to methods "for treating a human or animal patient in need of treatment for seborrheic dermatitis" (emphasis added to claim language). Giving the claim language its broadest reasonable interpretation consistent with the specification, we conclude that patients in need of treatment for seborrheic dermatitis reasonably may be treated for dandruff or any one or more of the other symptoms associated with seborrheic dermatitis. See In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989)("During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow"). Therefore, a prior art method that describes treating a patient for at least one symptom associated

with seborrheic dermatitis is construed to anticipate or render obvious a method for treating a patient in need of treatment for seborrheic dermatitis.

Seborrheic dermatitis is characterized by a variety of symptoms. The disorder is often associated with increased sebum production (seborrhea). (Exhibit A, page 1). Other symptoms may include: patchy lesions with margins, mild inflammation, and oily, yellowish scales. (Exhibit C, page 551).

Symptoms of seborrheic dermatitis range in degree from mild to severe. Although symptoms can be severe, "[a]symptomatic, fluffy white dandruff of the scalp represents the mild end of the spectrum of seborrheic dermatitis and has been referred to as pityriasis sicca." (Exhibit A, page 8). Thus, fluffy white flakes of the scalp are associated with both seborrheic dermatitis and simple dandruff. It follows that (1) treating dandruff, viz., fluffy white flakes, also constitutes treating a symptom of seborrheic dermatitis; and (2) an invention for treating dandruff would likely be useful for treating at least one symptom of seborrheic dermatitis. In fact, "[m]any cases of seborrheic dermatitis will respond to the same nonprescription drug regimen used to treat dandruff." (Exhibit C, page 550, column 2, lines 2-4).

Applicants submitted the declaration of Mitchell S. Wortzman with their Reply Brief. Wortzman concludes that "[o]ne of ordinary skill in the art would not find it obvious to use a certain composition to treat seborrheic dermatitis, merely because the same composition is used to treat dandruff." (Declaration of Mitchell S. Wortzman,

page 2, seventh paragraph). Again, we emphasize that the claimed invention is not directed to a method for successfully treating every symptom associated with, or eradicating, seborrheic dermatitis. Nor is it directed to a method of treating a human or animal patient having the classic, well-known disorder of patchy seborrheic dermatitis. (Exhibit A, page 8). The claimed invention is directed to a method for treating a patient "in need of treatment for seborrheic dermatitis." It cannot be gainsaid that "[m]any cases of seborrheic dermatitis will respond to the same nonprescription drug regime used to treat dandruff." (Exhibit C, page 550, column 2, lines 2-4).

New Grounds of Rejection

I. 35 U.S.C. § 102

Claim 39 is rejected under 35 U.S.C. § 102 as anticipated by Saint-Leger. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir.), cert. denied, 484 U.S. 827 (1987). "The reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it." In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990).

Saint-Leger is directed to a method for treating a human patient with a mixture of antifungal and antibacterial compounds. Saint-Leger states (column 2, lines 17-23):

> According to the invention, by the term 'antifungal agent' is intended any substance capable of inhibiting or preventing the growth of yeasts, in particular those found at the surface of the epidermis which is rich in sebaceous glands and especially at the surface of the scalp such as, for example, Pityrosporum ovale and varieties thereof (Pityrosporum orbiculare and Malassezia furfur).

Controlling the growth of Pityrosporum ovale appears to treat a symptom of seborrheic dermatitis. "Pityrosporum ovale, a lipophilic yeast which is a normal inhabitant of the skin, has been hypothesized to be the etiologic agent in seborrheic dermatitis." (Exhibit B, page 164). "Overgrowth of P. ovale may lead to inflammation." (Exhibit A, page 3). Therefore, controlling the growth of that microorganism appears to treat a symptom of seborrheic dermatitis.

In Example 6, Saint-Leger describes a method for treating a male human patient with a composition applied to the scalp, resulting in a change in the seborrhoea. Saint-Leger discloses that "individuals evaluated the variations in their seborrhoea, which could be increased, stable or reduced" (column 6, lines 23 and 24). Table II shows the results of that variation in seborrhoea. Many of the individuals experienced reduced seborrhoea or stable seborrhoea . (Id.). Therefore, Saint-Leger is directed to a method for treating a human patient with at least one symptom of seborrheic dermatitis. We here note that the active ingredients in the composition of Example 6, OCTOPIROX and IRGASAN, are the same active ingredients in the composition of Example 1 of that reference.

Example 1 of Saint-Leger discloses a method which fully meets the method recited in claim 39 using a specified 1-hydroxy-2-pyridone as active ingredient and an

anionic surfactant. Example 1 describes a method of treating a human patient with a shampoo comprising sodium lauryl ether sulfate containing 2.2 mol of ethylene oxide and 1-hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2-(1H)-pyridone, i.e., OCTOPIROX. (Saint-Leger, column 4, Example 1). Applicants' invention recited in claim 39 is directed to a method of treating a human or animal patient in need of treatment for seborrheic dermatitis by administering an effective amount of a composition comprising at least one 1-hydroxy-2-pyridone having formula (I) and at least one surfactant which may be an anionic surfactant. On this record, applicants do not deny that the 1-hydroxy-2-pyridone described by Saint-Leger in Example 1 is a species within the genus of compounds having formula (I) recited in claim 39. Further, applicants' specification teaches that anionic surfactants are preferred for use in the invention; and that examples of anionic surfactants include, inter alia, fatty alcohol ether sulfates that can be used in the form of water-soluble or water-dispensable salts, e.g., the sodium salt (specification, page 6, lines 4-6 and lines 18-31). Thus, Saint-Leger describes the composition recited in claim 39 comprising sodium lauryl ether sulfate and a specific 1-hydroxy-2-pyridone for use in treating a symptom of seborrheic dermatitis.[3]

II. 35 U.S.C. § 102 or 35 U.S.C. § 103

Claims 38-42 and 48 are rejected under 35 U.S.C. § 102 as anticipated by or, in the alternative, under 35 U.S.C. § 103 as unpatentable over Saint-Leger.

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[3] As stated in In re Ruscetta, 255 F.2d 687, 689-690, 118 USPQ 101, 104 (CCPA 1958), "it is axiomatic that the disclosure of a species in a reference is sufficient to prevent a later applicant from obtaining generic claims."

Example 1 of Saint-Leger anticipates claim 39. However, claim 38 adds a pH limitation to claim 39 which is not explicitly disclosed by Saint-Leger. As stated in In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977):

> Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on `inherency' under 35 U.S.C. § 102, on `prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products.

Example I of Saint-Leger reasonably appears to include the free form of a 1-hydroxy-2-pyridone, viz., OCTOPIROX, and an anionic surfactant. Applicants' specification states that when using the free form of the active ingredient, as Example 1 of Saint-Leger appears to be using, adjustment of pH to the skin-physiological range of approximately 4.5 to 6.5 is not necessary. (Specification, page 8, lines 29-33). Thus, it reasonably appears that Saint-Leger's Example 1 composition necessarily or inherently has a pH within the pH range of the composition recited in claim 38 and would not need to be adjusted to meet that range. Example 1 otherwise is identical to the claimed invention. On these facts, we believe that the evidence is sufficient to shift the burden of persuasion to applicants to show that the composition described in Example 1 of Saint-Leger does not necessarily or inherently have a pH within the range recited in claim 38. (Id.).

In any event, it would have been apparent to any person having ordinary skill in the art that the recited pH would be inherent in, or an obvious modification of, Saint-Leger's composition for use in treating a symptom of seborrheic dermatitis because Saint-Leger's composition is "formulated in a topically physiologically acceptable medium." (Saint-Leger, abstract). The Lange patent teaches using a physiologically acceptable acid in its second treatment phase. (Lange, abstract).[4] Lange states that the second phase "comprises a physiologically acceptable acid component, or mixture of such components." (Id.). Lange explains (column 5, lines 33-38):

> The acidity of the phase II solution is generally adjusted in the area of pH 3-6, preferred 4-5. The acidity of the phase II composition is adjusted in such a way that after application a situation is reached which is as much as possible in agreement with the natural pH of the skin.

Claim 40 limits claim 38 to at least one 1-hydroxy-2-pyridone or formula (I) comprising a cyclohexyl radical in the R^4 position. Saint-Leger teaches that a suitable antifungal agent for formulation according to his invention is CYCLOPIROX, i.e., 6-cyclohexyl-1-hydroxy-4-methyl-2-(1H)-pyridone (column 2, lines 28 and 29). Saint-Leger thus describes the 1-hydroxy-2-pyridone compound recited in claim 40.

Claim 48 depends from claim 38 and adds a limitation that "the pharmaceutical composition further comprises at least one additional surfactant chosen from anionic, cationic, nonionic, and amphoteric surfactants." In our judgment, that additional

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[4] As stated in In re Baxter Travenol Labs., 952 F.2d 388, 390, 21 USPQ2d 1281, 1284 (Fed. Cir. 1991), "extrinsic evidence may be considered when it is used to explain, but not expand, the meaning of a reference."

limitation does not serve to distinguish over Example 1 of Saint-Leger disclosing not only sodium lauryl ether sulfate containing 2.2 mol of ethylene oxide (anionic surfactant) but also coconut monoisopropanolamide (additional surfactant).

III. 35 U.S.C. § 103(a)

Claims 38-42, 48, and 53-66 are rejected under 35 U.S.C. § 103(a) in view of the combined teachings of Saint-Leger and Lange. The proper focus of an obviousness inquiry is whether "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." See Merck & Co., Inc. v. Biocraft Labs., Inc., 874 F.3d 804, 807, 10 USPQ2d 1843, 1846 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). The test for obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1971). Further, "in considering the disclosure of a reference, is it proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." In re Preda, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968).

Saint-Leger describes or reasonably would have suggested all aspects of the claimed invention for the reasons stated hereinabove except for the keratolytic agent of claims 53 and 59 and the lactic acid of claims 65 and 66. Saint-Leger discloses that

various types of adjuvants or additives are characteristically employed to formulate the compositions (column 3, lines 32-36). As stated by Saint-Leger (id., lines 38-43):

> Among these adjuvants or additives, especially representative are preservatives, stabilizing agents, pH regulators, osmotic pressure modifiers, emulsifying agents, sunscreen agents, antioxidants, fragrances, colorants, anionic, cationic, nonionic, amphoteric or zwitterionic surface-active agents or mixtures thereof, polymers, and the like.

Lange's invention "relates to the control of dandruff and similar scale forming conditions of the skin of the head" (column 1, lines 13-15). Lange discloses that "[o]ne may also use piroctone olamine [OCTOPIROX] in phase II because of its anti-seborrhoeic effect" (column 5, lines 65-66). Thus, Lange, like Saint-Leger, is directed to a method for treating a human patient with a symptom of seborrheic dermatitis.

Lange further discloses adding a keratolytic agent to his treatment composition. Lange teaches that organic acids, such as salicylic acid, "are known to give a therapeutic effect in the treatment of skin disease" (id., lines 24-32). Evidence submitted with the Reply Brief shows that salicylic acid was known as a keratolytic agent to persons having ordinary skill in the art at the time the invention was made. As indicated in the attached references, salicylic acid is a keratolytic agent. (Exhibit A, page 10; Exhibit B, page 166; Exhibit C, page 551). It would have been obvious for persons having ordinary skill in the art at the time the invention was made to add a keratolytic agent, like salicylic acid, to Saint-Leger's treatment compositions, to enhance their therapeutic effect.

Lange also discloses that lactic acid "plays an important physiological role in the structural stability and functional elasticity of the epidermis and keratine proteins" (column 8, lines 11-14). In that light, it would have been obvious for a person having ordinary skill in the art at the time the invention was made to add lactic acid to Saint-Leger's composition for its beneficial effects on the epidermis during treatment.

ORDER

For the reasons stated above, it is: ORDERED that

(1) the examiner's final rejections of claims 38-42, 48, and 53-66 are vacated; and

(2) new grounds of rejection are entered under the provisions of 37 CFR § 41.50(b).

This decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options

with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .
>
> (2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

VACATED: 37 CFR § 41.50(b)

Sherman D. Winters)
Administrative Patent Judge)
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)
Demetra J. Mills) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
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